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A request to correct the number "EP - A - 0077064" into "EP - A - 0077604" has been filed pursuant to Rule 88 EPC. A decision on the request will be taken during the proceedings before the Examining Division (Guidelines for Examination in the EPO, A-V, 2.2).

(54) **A device for release of a substance.**

(57) Described is a device for release of a substance from a solid preparation thereof to a flowing liquid during simultaneous parenteral administration of the liquid to a patient, which device comprises a connector (1) connectable into a system for parenteral administration of the liquid, and having an inlet (6) and an outlet (12) for the liquid and means for liquid communication of said inlet and outlet with a valve device (4, 5) which comprises a mobile valve core (5) having a bypass position providing for direct liquid flow from the inlet to the outlet of the connector and a working position providing for liquid flow from the inlet (6) of the connector into a releasable container (15) for the solid preparation. The device is characterized in that the valve core (5) has an outlet means (13A) and a separate inlet means (19A) simultaneously connectable to an inlet means (14) and a separate outlet means (18) respectively on the releasable container, the releasable container further having therein means (16) for conducting the liquid from the inlet thereof to a space where it will contact the solid preparation (17), and further to the outlet of the releasable container (18), and via the valve core in a flow path to the outlet (12) of the connector.

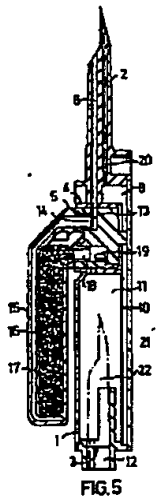

FIG.5

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Description

A device for release of a substance

The present invention is related to a device intended to be used in parenteral liquid administration to a patient, whereby one during such administration desires to release a substance, such as a drug, to the liquid.

A device by which drugs can be supplied to a parenteral liquid flow is shown by EP-B-0059694. Modified such devices are shown by EP-A-0077064, EP 85850141.4, EP-A-0100296 and WO 86/03416. A device for connection into a flow of infusion liquid, where the liquid by means of a valve can be led either via a vial for a drug to the patient or bypassing said vial, is shown by EP-A-0163387. A similar device having three operative valve positions, one for bypass of the liquid, one for dilution of a drug and one for emptying of a drug solution in an administration system, is shown by US 4534758. The two lastmentioned systems require that a liquid preparation ready for administration is formed in the vial before the valve is put in an administration position.

An object of the present invention is to achieve a device where a container for a dry drug preparation exchangeably can be connected to a liquid administration system, whereupon the liquid can be deviated and brought into contact with the drug thus that the drug is added to the liquid during administration of the liquid. A further object is to achieve a device where inadvertent deviation of the liquid is avoided when no drug container is connected.

Thus the device of the invention is a device for release of a substance from a solid preparation thereof to a flowing liquid during simultaneous parenteral administration of the liquid to a patient, which device comprises a connector connectable into a system for parenteral administration of the liquid, and having an inlet and outlet with a valve device which comprises a mobile valve core having a bypass position providing for direct liquid flow from the inlet to the outlet of the connector and a working position pro viding for liquid flow from the inlet of the connector into a releasable container for the solid preparation. The device of an invention is characterized in that the valve core has an outlet means and a separate inlet means simultaneously connectable to an inlet means and a separate outlet means respectively on the releasable container, the releasable container further having therein means for conducting the liquid from the inlet thereof to a space where it will contact the solid preparation, and further to the outlet of the releasable container, and via the valve core in a flow path to the outlet of the connector.

In a preferred embodiment of the invention the releasable container is a manoeuvre device for the valve core and the valve core has no other manoeuvre devices. Thus, when the valve core is rotatable in the valve device the releasable container may function as a handle gripping the end of the valve core by means of its inlet and outlet means. Inadvertent deviation of the liquid when no container is connected will be avoided by the invention in particular by this embodiment. Thus, risks of liquid spillage and air suction into the administration system are reduced.

Preferably the outlet and inlet of the valve core are connectable to the inlet and outlet of the releasable container by socket means, and preferably the socket means are tapered sockets fitting in tapered holes, and preferably the tapered sockets are the outlet means and inlet means of the releasable container and that the tapered holes are the inlet means and outlet means on the valve core.

In a specially preferred embodiment of the device a filter is arranged within the connector in the flow path from the valve in the working position to the outlet of the connector. Suitably the flow of liquid in the bypass position of the valve has dual flow paths to the outlet either through the filter or via the valve core.

Use of a device as described for release of a substance from a solid preparation thereof to a liquid during simultaneous parenteral ad ministration of the liquid to a patient is a further embodiment of the invention.

The invention is further described with the reference to the enclosed drawings where

Fig. 1 shows a device according to the invention in a bypass position,

Fig. 2 shows the device in fig. 1 in a working position,

Fig. 3 shows a connector in a bypass position,

Fig. 4 shows a connector in a bypass position in section along the line IV-IV in fig. 3,

Fig. 5 shows a section through a connector in a working position, with a container for a drug,

Fig. 6 shows an alternative rear portion of the connector in figs. 1-5.

With 1 is denoted a connector having an inlet via a transfer cannula 2 in one end thereof, that will usually be the upper end in use, and an outlet via a piercable membrane 3 in the opposite end thereof. In the connector there is a valve device consisting of a cylindrical valve housing 4 and a cylindrical valve core 5 turnable therein. Through the transfer cannula 2 an inlet channel 6 runs, which in the bypass position of the valve shown in fig. 4 opens into a first bypass channel 7 through the valve core, said bypass channel opening into a first inner space 8 in the connector. From the first inner space the liquid may, when the valve is in the bypass position, follow either of dual flow paths via a second bypass channel 9 through the valve core or via a bacteria filter 10, sealingly attached along its periphery to walls defining a second inner space 11 in the connector, to said second inner space which can be put in liquid connection with the outlet 12 of the connector via the membrane 3.

In the working position of the valve as shown in fig. 5, which position is at a 90° angle with the bypass position, the inlet channel 6 opens into a channel 13 through the valve core, which channel via an outlet

means of the valve core being a tapered opening 13A is in communication therein with tapered inlet socket 14 on a releasable drug container 15 being shaped substantially like an elongated box having its inlet socket 14 and a separate tapered outlet socket 18 adjacent to each other extending from one of the elongated faces thereof adjacent to one end thereof. Via an inlet channel 16 and a bed of granules 17 of the pharmaceutical preparation of the drug being released to the liquid, the liquid may circulate to the outlet socket 18 of the container, which socket via a tapered opening 19A in the valve core, being inlet means thereof, is in communication with a channel 19 through the valve core. Said channel opens into the first inner space 8, while the channel 19 has no opening directly into the second inner space 11, whereby the liquid at the working position of the valve can only pass via filter 10 to space 11. The cylindrical surface of the valve core 5 seals against the cylindrical surface of the valve housing 4. The valve core is secured against axial movement by a flange 5A thereon resting against an edge 4A in the valve housing and by an axial extension 5B to the valve core resting against a rear wall 21 of the connector 1. An airing channel 20 is in a manner known per se arranged through the transfer cannula 2. The first inner space 8 is limited by the rear portion 21 of the chamber and by side and end walls of the connector 1 and by the filter 10. A second transfer cannula for connection of a drip chamber via the membrane 3 to the connector is hinted with 22. Alternatively a drip chamber function may be built into the connector 1 or located at a different position in the system.

An alternative rear portion 23 has a hydrophobic filter 24 through which air from the downstream parts of the administration system can be let out.

While the device of the invention has a bypass position of the valve thereof and a working position in which the substance is released and administered it does not have a position in which the substance is merely reconstituted or dissolved while remaining in the releasable container.

The parenteral administration system may further comprise known details such as a liquid container (bottle or bag), conduits, injection ports, branchings, clasps, pumps, a cannula etc.

The device may be made as molded plastic parts, preferably in disposable design.

Claims

1. A device for release of a substance from a solid preparation thereof to a flowing liquid during simultaneous parenteral administration of the liquid to a patient, which device comprises a connector (1) connectable into a system for parenteral administration of the liquid, and having an inlet (6) and an outlet (12) for the liquid and means for liquid communication of said inlet and outlet with a valve device (4, 5) which comprises a mobile valve core (5) having a bypass position providing for direct liquid flow from the inlet to the outlet of the connector and a working position providing for liquid flow from the inlet (6) of the connector into a releasable container (15) for the solid preparation, characterized in that the valve core (5) has an outlet means (13A) and a separate inlet means (19A) simultaneously connectable to an inlet means (14) and a separate outlet means (18) respectively on the releasable container, the releasable container further having therein means (16) for conducting the liquid from the inlet thereof to a space where it will contact the solid preparation (17), and further to the outlet of the releasable container (18), and via the valve core in a flow path to the outlet (12) of the connector.

2. A device according to claim 1 characterized in that the releasable container (15) is a manoeuvre device for the valve core (5) and that the valve core has no other manoeuvre devices.

3. A device according to claim 1 or 2 characterized in that the outlet and inlet of the valve core are connectable to the inlet and outlet of the releasable container by socket means (14, 18).

4. A device according to claim 3 characterized in that the socket means are tapered sockets (14, 18) fitting in tapered holes (13A, 19A).

5. A device according to claim 4 characterized in that the tapered sockets (14, 18) are the outlet means and inlet means of the releasable container and that the tapered holes (13A, 19A) are the inlet means and outlet means on the valve core.

6. A device according to one or more of the preceding claims characterized in that a filter (10) is arranged within the connector in the flow path from the valve (4, 5), when in the working position, to the outlet (12) of the connector.

7. A device according to claim 6 characterized in that the flow of liquid in the bypass position of the valve has dual flow paths to the outlet either through the filter (10) or via the valve core (5).

8. Use of a device as claimed in any of claims 1 to 7 for release of a substance from a solid preparation thereof to a liquid during simultaneous parenteral administration of the liquid to a patient.

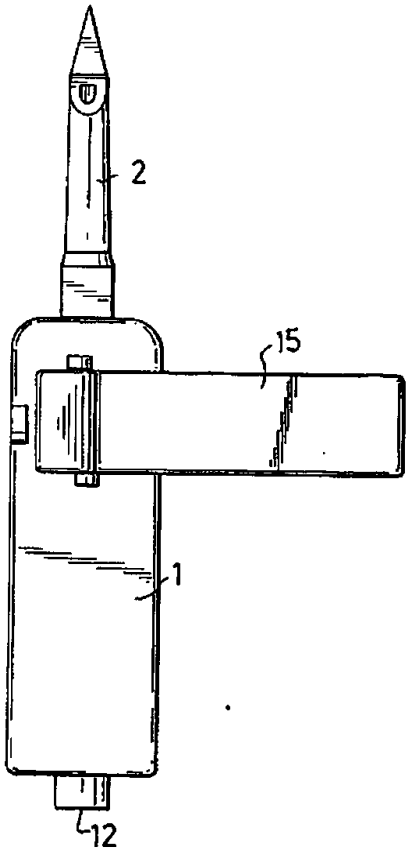

FIG.1

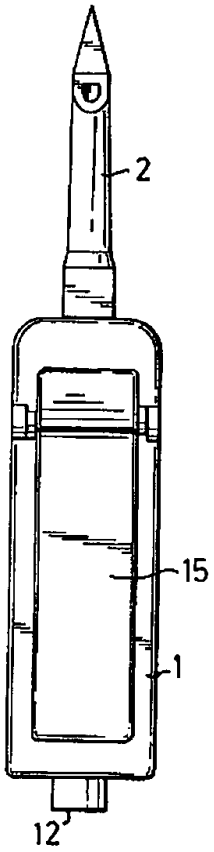

FIG. 2

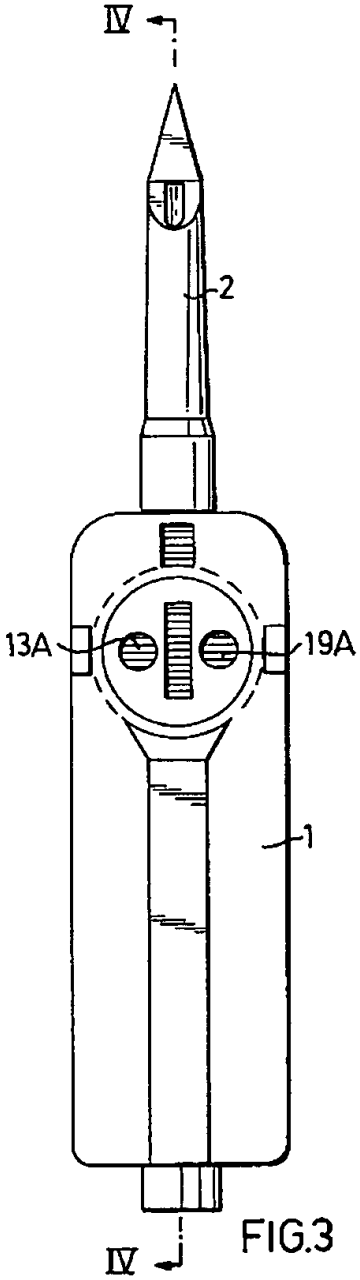

FIG.3

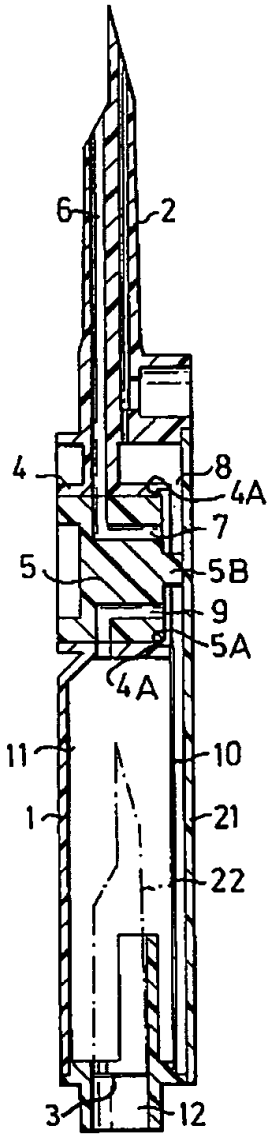

FIG. 4

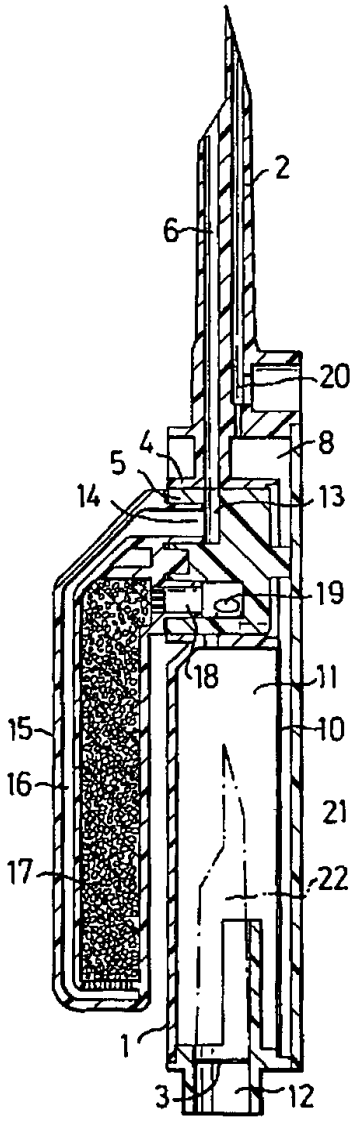

FIG.5

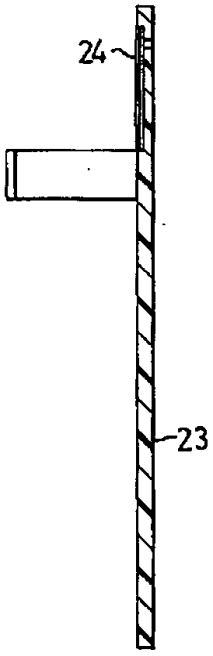

FIG.6

European Patent Office

EUROPEAN SEARCH REPORT

Application number

EP 87 85 0220

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int Cl.4)
Y,D	US-A-4 534 758 (AKERS) * Column 5, lines 1-14; figure 13 *	1-5,8	A 61 M 5/14 A 61 M 5/16
Y,D	WO-A-8 603 416 (BAXTER TRAVENOL LABORATORIES) * Page 46, lines 1-5; figure 19 *	1-5,8	
A,D	EP-A-0 059 694 (AB HÄSSLE) * Page 15, lines 25-33; figure 7 *	6	
A,D	EP-A-0 077 604 (ELI LILLY and CO.)		
A,D	EP-A-0 179 745 (K.-E.L. FALK)		TECHNICAL FIELDS SEARCHED (Int. Cl.4)
A,D	EP-A-0 100 296 (CIBA GEIGY AG)		A 61 M
A,D	EP-A-0 163 387 (IVAC CORP.)		

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	12-09-1987	EHRSAM F.J.A.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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